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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,444	12/30/2003	Orla McCullagh	S63.2B-10954-US01	2373

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EXAMINER	
SWEET, THOMAS	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,444	MCCULLAGH ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-52 have been considered but are moot in view of the new ground(s) of rejection. An alternative rejection under Shank et al appears below.

It is now admitted prior art to include a therapeutic polymer coating on a stent including non-genetic agent, genetic agent and cells since the Examiner's official notices of it being well known was not addressed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Shank et al. Shank et al discloses a stent (fig. 36 or 37) comprising:

a first section (fig. 32, 42a),

a second section (fig. 32, 42b) and

at least one securement member (fig. 32, 52i), the at least one securement member disposed about at least one region of the first section and at least one region of the second section (as shown in fig. 32), the at least one securement member having an uncrimped diameter (this is a product by process limitation in which member 52i is fully capable of having been manufactured from a circular tube) and a crimped diameter (as shown in fig. 32), the crimped diameter being less than the uncrimped diameter, when the at least one securement member is in

the crimped diameter at least a portion of an inner surface (at 132 and 134) of the at least one securement member is fixedly engaged to the at least one region of the first section (42a) and the at least one region of the second section (42b), in the crimped diameter a longitudinal seam (at 66i) at least partially separating the at least one region of the first section and the at least one region of the second section from each other (as shown in fig. 32) and spot welding the members 42 and 52 (as disclosed each of the members 42a and 42b is welded to the member 52, Col 10, lines 23-33 including motivation to weld at an opening such as the end of 52i at 66i for penetration).

However, Shank et al remains silent as to at least a portion of the at least one region of the first section and at least a portion of the at least one region of the second section comprise at least one weld positioned along the seam. Applicant has not disclosed that welding at the seam solves any stated problem or is for any particular purpose and appears from the disclosure to be functionally equivalent to spot welding. Moreover, it appears that the connection would perform equally well with welds at any location between the section and securement member. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to weld members 42a 42b and 52i at open end location such as at 66i because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Shank et al.

With regard to claim 2, at least one of the first section and second section is at least partially constructed of at least one wire (42 is wire).

With regard to claim 3, at least one of the first section and second section is at least partially constructed of a plurality of struts, wherein adjacent struts define at least one cell opening (such as shown in figs. 2, 36 and 37).

With regard to claims 6-9, at least a portion of the at least one region of the first section and at least a portion of the at least one region of the second section are fused together along the seam (42a, 42b and 52 are welded/fuses together).

With regard to claims 10 and 12, at least one strengthening member (member-a constituent part of any structural or composite whole, the bend in 52i above the seam at 66i bordering 53i), at least a portion of the at least one strengthening member positioned against (unitary with) the at least a portion of an inner surface of the at least one securement member (52i) and the at least one portion of at least one of the at least one region of the first section (42a) and the at least one region of the second section (42b).

With regard to claim 11, at least one weld is positioned between the at least a portion of the inner surface of the at least one securement member the at least one portion of at least one of the at least one region of the first section and the at least one region of the second section, and the at least a portion of the at least one strengthening member (as modified above).

With regard to claim 13, at least one of the first portion and the second portion of the at least one strengthening member has a length of about 2 mm (as long as Shanks securement member).

With regard to claims 14 and 20-23, Shank et al discloses the use of nitinol and stainless steel (col 5, line 13).

With regard to claims 15 and 24, Shank et al discloses of radiopaque materials (col 13, lines 37-46).

With regard to claims 16 and 17, the at least one strengthening member has a thickness, the thickness being about 0.015 inches (a 0.015 inch portion of 52i at the apex near 66i can be categorized as the strengthening member since unitary with 52i).

With regard to claim 18, Shank et al discloses self-expandable (col 1, lines 20-51 and col 12, lines 29-41) which is also inherently balloon expandable as well.

With regard to claim 19, the first section (42a) is a balloon expandable stent body and the second section (42b) is a self-expandable stent body (both are self-expandable which is inherently and fully capable of being balloon expandable as well since it is well known to seat a stent, filter, etc using a balloon after self-expansion).

With regard to claim, 25 and 26, Shank et al discloses a thickness being about 0.003 to about 0.007 inches (col 5, line 16).

With regard to claim 27, a third section (Col 10, lines 21-23), the at least one securement member (52) disposed about the at least one region of the first section (42a), the at least one region of the second section (42b), and at least one region of the third section, when the at least one securement member is in the crimped diameter the at least a portion of the inner surface of the at least one securement member is fixedly engaged to the at least one region of the first section, the at least one region of the second section and the at least one region of the third section.

With regard to claims 35-36, a plurality of securement members and a plurality of welds are shown based on fig. 37 having plural members such as 50g .

Claims 28-33 and 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shank et al in view Brown et al. Shank et al discloses a stent as discussed above. However, Shank et al remains silent as to including a therapeutic coating on the stent. It is admitted prior art to include a therapeutic polymer coating (such as polycarboxylic acids) on a stent for the purpose of treating the vessel with medicament at the point of implantation as demonstrated by Brown et al [0044]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporated a therapeutic polymer coating such as taught by Brown et al on the stent of Shank et al in order to provide medicament at the point of implantation in the vessel.

With regard to claims 30-32, Brown et al discloses the use of non-genetic agent, genetic agent and cells [0044]. It is admitted prior art to include for example heparin, DNA (which include the antisense portion of DNA), and donor cells on stents (which inherently includes autologous, allogeneic, and/or xenogeneic cells).

With regard to claim 37, Brown et al discloses heparin.

With regard to claims 38-42, anti-proliferative agents, anti-inflammatory agents, the antineoplastic/antiproliferative/anti-miotic agents, the anti-coagulants, the vascular cell growth promoters, the vascular cell growth inhibitors and the anesthetic agents are non-elected member of the Markush group of claim 30 rejected using heparin.

With regard to claims 45-48, the growth factors, the cell cycle inhibitors, the bone morphogenic proteins, and the molecules capable of inducing an upstream or downstream effect of a BMP are non elected member of the Markush group of claim 31 rejected using the antisense portion of DNA.

With regard to claims 49-52, polymer dispersion, polysaccharides, medical-grade biodegradable materials and the macromolecules are non-elected member of the Markush group of claim 33 rejected using the polycarboxylic acids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner AU 3738